

**Praluent (alirocumab)  
 Repatha (evolocumab)  
 Effective 01/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Alirocumab (Praluent) and evolocumab (Repatha) are human monoclonal antibodies that bind to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to LDL-receptors (LDLR) on the surface of hepatocytes to promote LDLR degradation in the liver. LDLR is the primary receptor that clears LDL; therefore, the decrease in LDLR levels by PCSK9 results in increased blood levels of LDL-C. By inhibiting PCSK9 binding to LDLR, these medications increase the number of LDLRs to lower LDL-C levels.

### Approvable Indications

#### Praluent (alirocumab)

1. Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with Heterozygous Familial Hypercholesterolemia (HeFH)
2. Clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein (LDL)-cholesterol (LDL-C).
3. To reduce the risk of serious cardiovascular events (e.g., MI, stroke and unstable angina) requiring hospitalization in adults with established cardiovascular disease.
4. Secondary prevention of cardiovascular events: To reduce the risk of MI, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease

#### Repatha (evolocumab)

1. Homozygous familial hypercholesterolemia: Adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-C
2. Primary Hyperlipidemia: Adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., maximum tolerated dose of statins), for the treatment of adults with primary hyperlipidemia, including heterozygous familial hyperlipidemia, to reduce LDL-C.
3. Prevention of cardiovascular events in patients with established cardiovascular disease: To reduce the risk of MI, stroke, and coronary revascularization in adults with established cardiovascular disease

4. Add-on treatment to diet alone or together with certain other therapies for patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).

### Coverage Guidelines

#### **Praluent (alirocumab)**

Authorization may be granted for members who are new to the plan currently receiving treatment with Praluent, excluding when the product is obtained as samples or via manufacturer's patient assistance program

**OR**

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Therapy prescribed by individuals with expertise in lipid management; this may include cardiologists, endocrinologists or primary care physicians
2. Patient is on maximal diet therapy
3. Patient is on maximum tolerated dose of high-intensity statin *and* ezetimibe for at least 3 months.

Adjunctive colesvelam (Welchol) should also be considered before initiating PCSK9 inhibitors:

- a. High-intensity statin therapy is defined as a daily dose which lowers LDL cholesterol level by approximately at least 50% on average.
- b. atorvastatin, 40 to 80 mg
- c. rosuvastatin, 20 to 40 mg

#### **Repatha (evolocumab)**

Authorization may be granted for members who are new to the plan currently receiving treatment with Repatha, excluding when the product is obtained as samples or via manufacturer's patient assistance program

**OR**

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Therapy prescribed by individuals with expertise in lipid management; this may include cardiologists, endocrinologists or primary care physicians
2. Patient is on maximal diet therapy
3. For the diagnosis of reduction in the risk of MI, stroke, and coronary revascularization in adults with established cardiovascular disease ONE of the following is required:
  - a. documentation that member will use in combination with an optimized regimen of lipid-lowering therapy (e.g., high-intensity statin) is required.
  - b. Lower doses are acceptable if a patient experienced adverse events and/or there is a drug interaction. Below are dose ranges for each of the medications:
    - i. Atorvastatin 10 - 80 mg daily
    - ii. Rosuvastatin 5 - 40 mg daily
    - iii. Simvastatin 20 - 40 mg daily
    - iv. Pravastatin 40 - 80 mg daily
    - v. Lovastatin 40 - 60 mg daily
    - vi. Pitavastatin 2 - 4 mg daily
    - vii. Fluvastatin 40 - 80 mg daily
    - viii. Ezetimibe 10 mg daily
  - c. Absence of statin and/or ezetimibe acceptable in the setting of intolerance
    - i. Statin intolerance defined as patients experiencing intolerable adverse events on at least three statins, including alternate day dosing.



- ii. In patients that have had clinically established rhabdomyolysis or severe CK elevation (at least 10 times the upper limit of normal), it is acceptable not to re-challenge with a statin
4. All other diagnosis:
- a. Patient is on maximum tolerated dose of high-intensity statin *and* ezetimibe for at least 3 months. Adjunctive colesevelam (Welchol) should also be considered before initiating PCSK9 inhibitors:
    - i. High-intensity statin therapy is defined as a daily dose which lowers LDL cholesterol level by approximately at least 50% on average.
    - ii. atorvastatin, 40 to 80 mg
    - iii. rosuvastatin, 20 to 40 mg
5. Previous use of Praluent is required except for the diagnosis of patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).

### **Continuation of Therapy**

Reauthorizations require physician attestation of improvement in member's LDL.

### **Limitations**

1. Initial approvals are issued for to 3 months
2. Reauthorizations are issued for 12 months

### **References**

1. Praluent (alirocumab) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2019.
2. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al; Writing Committee. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. 2016;68(1):92-125
3. Rosenson RS. Low density lipoprotein-cholesterol (LDL-C) lowering after an acute coronary syndrome. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed December 4, 2018
4. El Shahawy M, Cannon CP, Blom DJ, et al. Efficacy and safety of alirocumab versus ezetimibe over 2 years (from ODYSSEY COMBO II). *Am J Cardiol*. 2017;120(6):931-939.
5. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2019
6. Nissen SE, Stroes E, Dent-Acosta RE, et al; GAUSS-3 Investigators . Efficacy and tolerability of evolocumab vs ezetimibe in patients with muscle-related statin intolerance: the GAUSS-3 randomized clinical trial. *JAMA*. 2016;315(15):1580-1590
7. Sabatine MS, Giugliano RP, Keech AC, et al: FOURIER Steering Committee and Investigators. Evolocumab and clinical outcomes in patients with cardiovascular disease. *N Engl J Med*. 2017;376(18):1713-1722. 10.1056/NEJMoa1615664

### **Review History**

12/01/15 – Implemented

09/2015 – Reviewed

09/19/16 – Reviewed

09/18/17 – Reviewed

09/24/18 – Updated

06/16/19 – Added MD attestation

09/18/19 – New indication of prevention of CV events for Praluent

12/05/19 – Removed Specialty Medication language

11/17/2021 – Reviewed and Updated for Nov P&T; Repatha moves to non-preferred for 1/1/2022 implementation. Effective 01/01/2022



05/18/2022 – Reviewed and Updated for May P&T; reworded Repatha for criteria Previous use of Praluent is required except for the diagnosis of patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).

